Supreme Court, U.S.
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No. 97-1018

IN THE
Supreme Court of the United States

OCTOBER TERM, 1997

BARBARA MITCHELL and GREGORY MITCHELL,
Petitioners,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Seventh Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

Respondent Collagen Corporation urges the Court to deny certiorari on the question whether the Medical Device Amendments ("MDA") preempt state-law tort claims concerning medical devices that have received pre-market approval ("PMA") from the Food and Drug Administration ("FDA"). Although respondent takes this position on the ground that "[t]here is no conflict warranting review" (Opp. 7), it does not dispute the fact that it has twice petitioned for certiorari on the precise question presented here. According to respondent, review should be denied because (1) this Court recently denied several petitions allegedly involving the same issue (Opp. 6-7); (2) the post-*Medtronic* authorities are compatible with one another (Opp. 7-8); and (3) the decision below is correct (Opp. 8-11). None of these contentions has merit. Indeed, as we now show, the response to each of these contentions underscores the need for this Court to grant review and to put an end to the chaos in the lower courts on the question presented.

1. Respondent is correct that the Court recently denied several other petitions involving MDA preemption. Those petitions, however, either did not present the same question presented here or were procedurally defective. In two of the cases, including one in which respondent sought review, this Court did not have jurisdiction to review the petitions because the state appellate courts had not issued a final decision within the meaning of 28 U.S.C. 1257. *See Smith Indus. Medical Sys., Inc. v. Kernats*, No. 96-1405, and *Collagen Corp. v. Fiore*, No. 96-1611. Because those courts had held that a grant of PMA did not preempt the plaintiffs' tort claims against a device manufacturer and remanded the cases for trial, *Fiore v. Collagen Corp.*, 930 P.2d 477 (Ariz. App. 1996), *review denied*, No. CV-96-044-PR (Ariz. Jan. 14, 1997), *cert. denied*, 1998 WL 6291 (U.S. Jan. 12, 1998); *Kernats v. Smith Indus. Medical Sys., Inc.*, 669 N.E.2d 1300 (Ill. App.), *appeal denied*,

675 N.E.2d 634 (Ill. 1996), *cert. denied*, 1997 WL 107232 (U.S. Jan. 12, 1998), the decisions were quintessential non-final judgments and this Court lacked the power to consider them. *See Jefferson v. City of Tarrant*, 118 S. Ct. 481 (1997). Indeed, the Solicitor General urged this Court to deny the petition in *Smith Industries v. Kernats* principally on the ground that this Court lacked jurisdiction, noting also that the Illinois Court of Appeals' no-preemption holding was correct. Brief of the United States as Amicus Curiae in No. 96-1405, at 10-17.

Another petition recently denied--*Martin v. Telectronics Pacing Sys., Inc.*, No. 96-1749--involved an investigational device, rather than a PMA device. Thus, review by this Court in *Martin* would likely have left unresolved the effect of a PMA, which is the principal sphere of confusion after *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). In addition, the investigational device cases involve, among other things, an FDA regulation that, on its face, appears to preserve state-law liability with respect to investigational devices. *See* 21 C.F.R. 50.20. Therefore, the Court could have decided *Martin* without resolving the broader questions involving PMA devices. *Cf. Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1487 n.3 (1995)(resolving preemption case on narrow grounds specific to particular case, and not addressing broader preemption questions). Here, however, if this Court holds in favor of petitioners, either on the ground that FDA device approval is not sufficiently specific to preempt or that the MDA does not preempt state-law claims of general applicability (*see* Pet. 16-20; 21 C.F.R. 808.1(d)(1)), the decision will provide the certainty for all medical device cases for which the lower courts have been searching since *Medtronic*.[1]

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[1] Petitioners recognize that *Eddy v. Polymer Technology Corp.*, 674 (continued..)

By contrast with *Smith Industries* and *Collagen Corp. v. Fiore*, the petition here involves a ruling that finally disposes of all of petitioners' claims. It squarely presents the question absent in *Martin*: MDA preemption involving a PMA device. And, as opposed to *Eddy*, it is the result of two detailed--albeit, in our view, incorrect--decisions of the Seventh Circuit, whose rationale is generally quite clear. *See* Pet. App. 1a-26a, 53a-87a.

2. In light of its earlier efforts to obtain review on the question presented, respondent's claim that there is "decisional uniformity" (Opp. 8) in the lower courts should be taken for what it is: an attempt to avoid review of a decision favorable to it. As shown in the petition (at 12-15), the conflict in the state and federal appellate courts is deep and growing.

Respondent also asserts that review is not warranted because the decisions involving PMA devices that are in conflict with the Seventh Circuit's ruling are from intermediate state appellate courts. Opp. 7. That claim is both incorrect and misleading for several reasons.

a. First, even on its own terms, respondent's argument is flatly wrong. In *Green v. Dolsky*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997), the Pennsylvania Supreme Court held that the MDA's PMA process preempts some product liability claims, **but not other such claims**, a point that was not lost on respondent, which filed a cross-petition in No. 96-1451, seeking a complete no-

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(...continued)

A.2d 323 (Pa. Super. Ct. 1995)(Table), *appeal denied*, 692 A.2d 566 (Pa. 1997)(Table), *cert. denied*, 1998 WL 15432 (U.S. Jan. 20, 1998), No. 97-26, an unpublished decision from the Pennsylvania Superior Court, found preemption of claims involving a PMA device. However, the rationale for that decision is unclear, which made the case a questionable vehicle for resolving the question presented.

preemption ruling--like the one it obtained in the Seventh Circuit below. *See Collagen Corp. v. Green*, 117 S. Ct. 1695 (1997).

b. Second, respondent is able to assert that the decisional conflict is limited to intermediate appellate courts only by dismissing the rulings in *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997), as involving "very different circumstances" (Opp. 8). But that characterization misses the point. Although *Oja* did not involve a PMA device, it concerned a device for which the FDA had mandated a specific warning (*i.e.*, a specific FDA "requirement" of the kind **not** required by the FDA for respondent's device in this case). The Tenth Circuit agreed with the defendant that the FDA-mandated warning was specific enough under *Medtronic* to be a preemptive federal "requirement." *Oja*, 111 F.3d at 789. It then held, however, that none of the plaintiff's claims were preempted, regardless of the specificity of the FDA requirement, because the plaintiff's "negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer 'to inform users and purchasers of potentially dangerous items of the risks involved in their use.'" *Id.* (quoting *Medtronic*, 116 S. Ct. at 2258)(internal citations omitted). This holding is directly at odds with the decision below, as the Seventh Circuit itself noted (Pet. App. 19a n.4), and it applies to a PMA device as much as it applies to any other medical device regulated by the MDA.

The same is true of the rationale of the Kentucky Supreme Court in *Niehoff*, which concerned a class III medical device, albeit one that was marketed under an investigational exemption. Like the Tenth Circuit in *Oja*, *Niehoff* held that none of the plaintiff's claims were preempted, regardless of the potential preemptive effect of FDA regulations, because "Kentucky's strict liability case law and statutes [on which the plaintiff relied] are laws of general applicability to all products and fall beyond the scope of the federal preemption under [21

U.S.C.] §360k." *Niehoff*, 950 S.W.2d at 822. Thus, *Niehoff* makes clear that tort claims involving medical devices--including PMA devices--are not preempted if they are premised on state law of general applicability. *Id.* Indeed, a recent no-preemption decision from the intermediate appellate court in Kentucky understands *Niehoff* (and *Oja*) in precisely that manner. *See Leslie v. Cincinnati Sub-Zero Prods., Inc.*, ___ S.E.2d ___, 1998 Ky. App. Lexis 5, *10-*12 (Ky. App. Jan. 30, 1998).

c. Finally, respondent does not, because it cannot, challenge the precedential importance of the intermediate appellate rulings cited by petitioners. With the exception of *Baird v. American Medical Optics*, 693 A. 2d 904, 909-10 (N.J. Super.), *certification granted*, 700 A.2d 879 (N.J. 1997), each of the rulings upon which the petition relies is binding in its geographical region. *See, e.g., Kernats v. Smith Indus. Medical Sys., Inc.*, 669 N.E.2d 1300 (Ill. App.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. App. 1996), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997). Indeed, respondent does not dispute what is perhaps petitioners' most telling evidence of post-*Medtronic* confusion--that, in addition to the conflict among appellate decisions from different jurisdictions around the Nation, there are splits of authority **within** Illinois (depending on whether the case is in state or federal court) and California (depending on geography) on the same question raised in the petition. *See* Pet. 14 n.5; *compare also Niehoff*, 950 S.W.2d 816 (Kentucky Supreme Court: no preemption), *with Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997)(Sixth Circuit: complete preemption), *cert. denied* 1998 WL 15431 (U.S. Jan 20, 1998).

3. Finally, respondent claims that review should be denied because the decision below is correct. Opp. 9-11. Even if "correctness" were a reason for denying review on an important question of federal law, that rationale would not apply here,

where, as explained above and in the petition, the lower federal and state appellate courts are in disarray. *But see Lewis v. Brunswick Corp.*, 118 S. Ct. 439 (1997)(granting plaintiff's petition on preemption question, despite virtual unanimity of lower court authority favorable to defendant).

Petitioners need not reprise the reasons why the decision below is drastically at odds with this Court's decision in *Medtronic*. For present purposes, the question is not whether the preemption issue was handled properly below, but whether the Court should consider that issue at all, the answer to which is apparent from the confusion in the lower courts. However, if the merits of the Seventh Circuit's decision enter into the certiorari calculus, petitioners have the better of the argument (*see* Pet. 16-20), and are joined by the FDA, which recently reiterated to this Court its "longstanding position" that the MDA does not preempt tort claims involving injuries from devices that have obtained PMA. *See* Brief of the United States as Amicus Curiae in No. 96-1405, at 1a. That the agency charged by Congress with implementing the MDA believes that the decision below is incorrect underscores the need for review by this Court before petitioners' rights to compensation--and the rights of similarly situated plaintiffs--are forever lost. *See Medtronic*, 116 S. Ct. at 2255-56 (deferring to FDA's preemption views); *id.* at 2261 (Breyer, J., concurring)(same).[2]

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[2] In *Worthy v. Collagen Corp.*, ___ S.W.2d ___, 1998 Tex. Lexis 22 (Tex. Feb. 13, 1998), the Texas Supreme Court held all of the plaintiffs' claims preempted on a rationale similar to that of the decision below, but noted the conflict in lower court authority. *Id.* at *37-*44. In doing so, that court dampened the hopes of the Solicitor General that the FDA's recently reiterated view that the PMA process does not preempt state tort claims would "reduce the current uncertainty respecting Section 360k's preemptive effect." Brief of the United States as Amicus Curiae in No. 96-1405, at 20. The Texas Supreme Court acknowledged that the FDA's views were entitled to significant weight, but nonetheless rejected them. *Worthy*, 1998 Tex. Lexis at *45-*48.

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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